UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

THE PEOPLE OF THE STATE OF NEW YORK Plaintiff, v. ACTAVIS, PLC, and FOREST LABORATORIES, LLC, Defendants.	Public Version Case No.: 14-CV-7473 (RWS)

NEW YORK'S OPPOSITION TO DEFENDANTS' MOTION TO DISMISS AMENDED COMPLAINT

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INTRODUCTION

Defendants' motion to dismiss the Amended Complaint must be denied, regardless of whether the Court grants New York's motion for a preliminary injunction. Given that the Court must review the Amended Complaint, and interpret all the alleged facts in the light most favorable to New York, there is no basis for dismissal. Moreover, New York demonstrated at the preliminary injunction hearing that it is likely to succeed in proving that Defendants' conduct harms competition and constitutes exclusionary conduct, in violation of the antitrust laws. In that case, New York would clearly have met the vastly lower standard to defeat a motion to dismiss.

Defendants' motion fails to accept the facts as pleaded in the Amended Complaint and instead infuses their papers with new facts. Even if the Court were inclined to accept Defendants' characterizations of these facts, the appropriate time to consider such issues would be on a motion for summary judgment – not a motion to dismiss. On a motion to dismiss, all facts must be presumed in New York's favor. And given that there has only been limited discovery in this action, prior to any motion for summary judgment New York would be entitled to further discovery that it has not yet had the opportunity to pursue.

Granting the motion to dismiss in this case would suggest that forced switches like Defendants' are always legal, *regardless* of the impact on competition, *regardless* of the market position of the drug manufacturer, *regardless* of the impact of the conduct on patients, *regardless* of the impact on health plans, and *regardless* of the costs imposed on consumers and society in each individual case. That cannot be the law, and under prior decisions, including the highly analogous precedent of *Abbott Labs*, that is not the law.

While significant irreparable harm will occur if New York's preliminary injunction motion is not granted, the ramifications of dismissing this action on the pleadings would be even more severe. Such a dismissal could be interpreted as tantamount to a blank check for pharmaceutical companies to implement "forced switches." In the future, if Defendants have their way, patients may be forced to change medications on a routine basis just prior to generic entry for their drug – not because of market forces or sound medical judgment – but rather because of drug manufacturers' perceived newly found right to manipulate them. The expectation that expiring patents will soon lead to lower-cost drugs will be replaced by an expectation of routine regulatory gamesmanship just before generic entry, defeating efforts to control public health costs through increased competition.

Defendants' forced switch will take decisions concerning the administration of Namenda away from physicians and caregivers and, instead, place them in the hands of a drug manufacturer motivated solely by the goal of boosting company profits. New York's action is an opportunity to prevent this unlawful, anticompetitive tactic before it harms patients and competition. Regardless of whether the Court decides to grant the motion for preliminary relief, the Court should deny Defendants' motion to dismiss on the grounds that Defendants have no absolute right to engage in this behavior, and that the legality of such conduct depends on factual issues that are fully within this Court's power to resolve.

The legal contentions in Defendants' motion to dismiss may be disposed of relatively quickly. Among other things:

- Under well-established law, Defendants' patent does *not* confer antitrust immunity for conduct that otherwise violates the antitrust laws.
- In this action, New York asserts a standard monopolization case based on foreclosure of competition through exclusionary conduct, and a traditional claim for Defendants' unlawful agreement in restraint of trade.
- New York does not seek to force Defendants to deal with any competitors.
- The withdrawal of Namenda IR is neither competitive "innovation" nor "competition on the merits." Namenda XR may be preferred by some patients, but the value of any innovation concerning Namenda XR should be left to the market to decide.
- The injunction New York seeks will not in any way put the Court in charge of running or regulating a business, and it is not extraordinary relief.

Accordingly, the motion to dismiss should be denied.

BACKGROUND

New York's Amended Complaint alleges, and the evidence at the preliminary injunction hearing clearly showed, that Defendants are bent on implementing a forced-switch scheme to coerce patients and physicians into switching from the immediate release form of Namenda IR to Defendants' newer extended release version, Namenda XR. The allegations in the Amended Complaint establish that the effect of the forced switch would be to substantially foreclose competition in the market for NMDA antagonists by interfering with the ability of generic manufacturers to enter the market next summer. The forced-switch strategy has absolutely no redeeming quality. It is anti-

patient, anti-consumer, it increases healthcare costs, and it reduces patient and physician choice. It is not innovation. It is market manipulation and abuse of monopoly power.

For a complete factual background, beyond the facts provided in the Amended Complaint, we refer the Court to, and incorporate by reference, New York's Post-Hearing Proposed Findings of Fact (Nov. 18, 2014) ("NY PFOF") ¶¶ 16-194 and New York's Post-Hearing Proposed Conclusions of Law (Nov. 18, 2014) ("NY PCOL") ¶¶ 25-128.

Defendants' motion turns on documents and factual disputes outside the Amended Complaint's allegations, and New York notes that it has not yet had the opportunity to take full discovery. The limited discovery that has taken place so far, however, has allowed New York to present evidence at the hearing sufficient to show a likelihood of success on the merits, the public interest, and irreparable harm – much more than is needed to defeat a motion to dismiss. NY PFOF ¶¶ 16-152, 169-194.

Specifically, New York has alleged and presented evidence that:

- Competition by generic manufacturers of Namenda IR will be substantially harmed by the forced switch because they will be unable to make use of a nationwide set of generic drug substitution laws, their most cost-effective means of competing. NY PFOF ¶¶ 108-123, 126, 129-133; Am. Compl. ¶¶ 70-72, 86-87, 96-104, 114, 116.
- Defendants' publicly-stated purpose for the forced switch is to dramatically reduce the effectiveness of competition from generic Namenda IR. NY PFOF ¶¶ 11-12, 41-44, 63, 130-131, 156; Am. Compl. ¶ 87-88. It is reasonable to conclude that this would be the actual effect. To the extent that Defendants have proffered alternative explanations for their plan, these explanations never

surfaced before the commencement of this investigation and action, and they are clearly post-hoc, made-for-litigation rationalizations.

- Defendants' plan for limited distribution of Namenda IR through Foundation Care is not materially different from Forest's pre-litigation plan to fully discontinue Namenda IR. Defendants themselves anticipated that only 3% of patients will make use of the program, resulting in a "forced switch" that is as unambiguous as if Namenda IR were fully discontinued. Defendants' own press release emphasizes the small differences between the two plans, by referring to the new plan as the "discontinuation of the general sale and distribution" of Namenda IR. NY PFOF ¶¶ 145-152; Am. Compl. ¶¶ 83-84, 114-118.
- Defendants' agreement with Foundation Care contains an anticompetitive provision that restrains trade because Defendants prohibit Foundation Care from freely selling Namenda IR to patients who have a lawful prescription. The intended goal and actual effects of such restriction is to harm competition and foreclose entry by generics. NY PFOF ¶¶ 145-152; Am. Compl. ¶¶ 125, 127.
- As a result of Defendants' conduct, a large number of physicians will have reduced choice and feel compelled not to prescribe the drug they believe is in the best interests of their patients. NY PFOF ¶¶ 57-58, 159, 171, 180-181, 184; Am. Compl. ¶¶ 42, 78-80.

- Caregivers and vulnerable Alzheimer's patients will be harmed by the loss of choice and by the need to change routines, as a result of the forced switch. NY PFOF ¶¶ 169-184; Am. Compl. ¶¶ 5-6, 42, 77-79, 90, 118.
- Private insurers and the federal government will be harmed by the forced switch as a result of the dramatically reduced use of generic drugs and thus significantly increased health care costs. NY PFOF ¶¶ 65-66, 84, 91; Am. Compl. ¶¶ 6, 21, 23, 39, 71, 92, 111-112, 132.

ARGUMENT

Regardless of the Court's decision on the preliminary injunction motion, the motion to dismiss must be denied. It is well-settled that "the standard in deciding a motion for a preliminary injunction is more stringent than that used in a motion to dismiss." *Fashion Television Assocs. v. Spiegel, Inc.*, 849 F. Supp. 19, 22 n.7 (S.D.N.Y. 1994). This is because, "unlike a preliminary injunction motion, dismissal pursuant to Rule 12(b)(6) is not based on whether Plaintiff is likely to prevail, and all reasonable inferences must be viewed in a light most favorable to Plaintiff." *Lawrence v. Town of Brookhaven Dep't of Hous.*, 2007 U.S. Dist. LEXIS 94947, at *36 (E.D.N.Y. Dec. 26, 2007) (citing *Cleveland v. Caplaw Enters.*, 448 F.3d 518 (2d Cir. N.Y. 2006)); *see also Palladino v. City of New York*, 2008 U.S. Dist. LEXIS 86757, at *10 (S.D.N.Y. Sept. 30, 2008); *Peel v. Crew*, 1996 U.S. Dist. LEXIS 18525, at *20-23 (S.D.N.Y. Dec. 12, 1996) (different standards for injunction and dismissal motions). "Dismissal is inappropriate unless it appears beyond doubt that the plaintiff can prove no set of facts which would entitle him or her to relief." *United States CFTC v. Wilson*, 2014 U.S. Dist. LEXIS

88111, at *28 (S.D.N.Y. June 26, 2014) (quoting *Sweet v. Sheahan,* 235 F.3d 80, 83 (2d Cir. 2000)).

The outcome of the preliminary injunction motion, *e.g.,* if based on lack of irreparable harm or another element not related to the merits of the action, would not indicate any inability of New York to state a claim. In any case, denial of the motion to dismiss is appropriate – and full discovery should proceed so that the Court may undertake a full examination of the merits.

Moreover, regardless of whether the Court finds that New York is likely to succeed on the merits, it should not dismiss the complaint. "Given this very different standard by which a court assesses a motion to dismiss, it may find . . . that while a party has not established a likelihood of success on the merits for a preliminary injunction, it still presents a cognizable legal claim for a remedy which may be proved at trial." *Henrietta D. v. Giuliani,* 1996 U.S. Dist. LEXIS 22373, at *36 (E.D.N.Y. 1996). To prevail on this motion to dismiss, New York "is not required to prove her case; she must simply establish that the allegations in the Complaint are sufficient to render her claims plausible." *Brown v. New York*, 975 F. Supp. 2d 209, 235 (N.D.N.Y 2013) (quotations and citations omitted); *Wilson,* 2014 U.S. Dist. LEXIS 88111 at *28.

That is particularly true here where Defendants' motion raises significant factual issues. Where, as here, the motion goes beyond the four corners of the Amended Complaint, it should be denied and the issues handled in a more proper motion for summary judgment. *See* Fed R. Civ. P. 12(d); *see, e.g.,* Defs.' Mem. at 3, 7 & n.4 (citing transcript of earnings call and press releases). Dismissal is particularly inappropriate where, as here, the motion to dismiss itself liberally relies upon a factual record that has

only been partially developed in limited discovery. *See, e.g., Environmental Servs. v. Recycle Green Servs.*, 7 F. Supp. 3d 260, 270 (E.D.N.Y. 2014) (declining to treat a dismissal motion as motion for summary judgment, because "plaintiffs . . . are entitled to discovery before having to oppose a motion for summary judgment") (quoting *Hoy v. Inc. Vill. of Bayville*, 765 F. Supp. 2d 158, 164 (E.D.N.Y. 2011)).

New York would be severely prejudiced if its claims were dismissed without it being permitted to take additional discovery. New York has had incomplete discovery of the Defendants. Their repeated claim to have produced one million pages is misleading given that the overwhelming majority of those documents consist of the voluminous NDA filing.[1] Moreover, New York has not yet pursued discovery of health plans and pharmacy benefit managers ("PBMs"), or of generic manufacturers, physicians or caregivers. While New York did seek and obtain voluntary testimony from several such individuals, that is no substitute for the opportunity to employ more wide-ranging discovery of these important market players. Similarly, New York would need further discovery of Foundation Care, the mail-order pharmacy that Defendants have chosen as their sole, limited distributor for Namenda IR.

Under these circumstances the motion to dismiss should be denied. And if, *arguendo*, the Court finds any technical pleading deficiencies in the Amended Complaint, New York should be afforded the right to cure. *See* Fed. R. Civ. P. 15(b).

[1] Roughly 30,000 documents were produced by Defendants from custodian files specifically for New York's investigation or litigation, which is a very small production by modern litigation standards, especially in a monopolization case. There are several important avenues of discovery that remain necessary and some may depend on the specifics of the Court's ruling on the preliminary injunction motion.

I. Defendants' Patent Does Not Confer Antitrust Immunity

Defendants' principal argument – that their patent rights give them an absolute right to sell, or not sell, as they see fit, and that their conduct is essentially "above the law" – is wrong as a matter of law. *See* Defs.' Mem. at 8-11. To begin with, the patent laws merely grant Defendants the right to exclude others from practicing their patent, which is not at issue here. 35 U.S.C. §154; *Motion Picture Patents v. Universal Film*, 243 U.S. 502, 501 (1917) ("It has long been settled that *the patentee receives nothing from the law which he did not have before*, and that the only effect of his patent is to restrain *others* from manufacturing, using or selling that which he has invented.") (emphasis added).

Defendants ignore *Microsoft* and other relevant authorities, instead relying on a recitation of generalities concerning the scope of its patent rights. In essence, Defendants confuse the lawful scope of their patent exclusivity with a purportedly limitless right to act without regard to antitrust laws. *See* Defs.' Mem. at 8-10. However the law is clear: Intellectual property rights do not confer absolute antitrust immunity. *See United States v. Microsoft Corp.*, 253 F.3d 34, 63 (D.C. Cir. 2001) (rejecting Microsoft's "border[line] . . . frivolous" argument of absolute antitrust immunity arising from intellectual property). Indeed, the D.C. Circuit warned that Microsoft's (and now Forest's) argument was "no more correct than the proposition that use of one's personal property, such as a baseball bat, cannot give rise to tort liability." *Id.*

A. Defendants' Patent Monopoly Does Not Entitle Them To Engage In Exclusionary Conduct

It is well established that the patent laws do not confer blanket immunity to engage in antitrust violations. *See* NY PCOL ¶¶ 84-90. As noted, this same argument

was rejected by the D.C. Circuit *en banc* in *Microsoft*, 253 F. 3d at 63 (no "absolute and unfettered right to use its intellectual property as [one] wishes.") On the contrary, it is well-settled that "[i]ntellectual property rights do not confer a privilege to violate the antitrust laws." *Id.* (quoting *In re Indep. Serv. Orgs. Antitrust Litig.*, 203 F.3d 1322, 1325 (Fed.Cir.2000)); *see also In re ISO Antitrust Litigation v. Xerox*, 203 F.3d 1322, 1327 (Fed. Cir. 2000) ("patent holder cannot use his statutory right to refuse to sell patented parts to gain a monopoly in a market beyond the scope of the patent"); *Atari Games Corp. v. Nintendo of America, Inc.*, 897 F.2d 1572, 1576 (Fed. Cir. 1990) ("[A] patent owner may not take the property right granted by a patent and use it to extend his power in the marketplace improperly, i.e. beyond the limits of what Congress intended to give in the patent laws. The fact that a patent is obtained does not wholly insulate the patent owner from the antitrust laws."); NY PCOL ¶¶ 84-90.

Defendants also ignore the most factually analogous case, *Abbott Labs v. Teva Pharm. USA, Inc.*, 432 F. Supp. 2d 408 (D. Del. 2006), which rejected a similar motion to dismiss. *Abbott Labs* held that an antitrust inquiry into the effect of Defendants' product withdrawal and formulation changes was "justified" on account of Abbott's efforts to game the framework of federal patent and state substitution laws in a manner similar to the allegations here. *Id.* at 422; Am. Complaint ¶¶ 28-43, 64-104. The validity of a similar claim has also been acknowledged within this District. *Xerox Corp. v. Media Scis. Int'l, Inc.*, 511 F. Supp. 2d 372, 388 (S.D.N.Y. 2007) ("[P]roduct redesign, when it suppresses competition and is without other justification, can be violative of the antitrust laws.")

Instead of addressing *Microsoft*, *Abbott Labs*, or the other authorities that govern Forest's forced switch scheme, Defendants instead cite authorities that stand for nothing more than the uncontroversial principle that "mere non-use of a patent can never be an antitrust violation in and of itself." Defs.' Mem. at 9 & n.5 (quoting, *inter alia*, III Phillip E. Areeda & Herbert Hovenkamp, *Antitrust Law: An Analysis of Antitrust Principles and Their Application* ¶ 708a, at 298 (3d ed. 2008)). The forced switch scheme is not "mere non-use of a patent," but rather the proverbial misused "baseball bat" of which the D.C. Circuit warned. *Microsoft*, 253 F. 3d at 63.

The allegations in the Complaint show that Defendants implemented the forced switch to prevent loss of sales to future generic versions of Namenda IR that are scheduled to enter the market next summer. NY PFOF ¶¶ 41-46, 50, 79, 120, 126; Am. Complaint ¶ 74. Indeed, Defendants' CEO publicly declared that the forced switch was intended to limit competition, by making the abrupt "patent cliff" of lost sales to the generic market into a "slow decline":

> [I]f we do the hard switch and we've converted patients and caregivers to once-a-day therapy versus twice a day, it's very difficult for the generics then to reverse-commute back, at least with the existing Rxs. They don't have the sales force, they don't have the capabilities to go do that. It doesn't mean that it can't happen, it just becomes very difficult. It is an obstacle that will allow us to, I think, again, go into to a slow decline versus a complete cliff. NY PFOF ¶ 63; Am. Compl. ¶ 87.

This fact alone would be sufficient to deny a motion for summary judgment – let alone a 12(b)(6) motion – since there is plainly a genuine issue of material fact as to whether the forced switch constitutes a product withdrawal that "suppresses competition and is without other justification." *Xerox*, 511 F. Supp. 2d at 388. In addition to this statement by Defendants' CEO, there are ample allegations in the Complaint that show

that the forced switch scheme was intended to manipulate the market and exclude generic competition. *See, e.g.*, NY PFOF ¶¶ 30-92; Am. Compl. ¶¶ 2-6, 64-97.

In addition, the law is clear that attempts by patent-holders to exercise their patents in a way that effectively extends the exclusionary scope of the patent into the future are unlawful. *Cf. In re ISO Antitrust Litigation v. Xerox*, 203 F.3d 1322 (Fed. Cir. 2000) ("patent holder cannot use his statutory right to refuse to sell patented parts to gain a monopoly in a market beyond the scope of the patent"). That is essentially what Defendants are seeking to do here.

While the Second Circuit has held that merely introducing a new product – without withdrawing the old product – is not generally a basis for antitrust liability, this rule only applies where both products are left on the market and there is "free choice" and no "element of coercion" of customers, such as impeding customer access to the prior version of the product. *Berkey Photo v. Eastman Kodak*, 603 F.2d 263, 288 (2d Cir. 1978); NY PCOL ¶¶ 42-47, 80.

Here Defendants have placed obstacles in the way of customer access to the prior version of their product, Namenda IR, by "discontinuing the general sale and distribution of Namenda IR" and only making the drug available (after the filing of this litigation) through Foundation Care in a highly restricted manner. *See* NY PCOL ¶ 44. Defendants know that by restricting the availability of branded Namenda IR in this way they have effectively ensured that less than 3% of patients will use it. Currently physicians are prescribing Namenda IR in over 50% of cases, and Defendants' own economist admitted at the hearing that it is reasonable to infer that these physicians "prefe[r]" Namenda IR in these cases. *See id.* As a result, Defendants cannot take advantage of the rule in *Berkey*

Photo preventing liability where the defendant has left both products on the market and allowed customers to make a "free" and unimpeded choice.

B. New York Alleges Foreclosure And Exclusionary Conduct, Not "Alchemy" Under *LinkLine*

Defendants' "alchemy" argument is based on a flawed theory that – as long as each component act of an anticompetitive scheme is legal – the scheme in its entirety is immune. *See* Defs.' Mem. at 10. *Abbott Labs* specifically rejected the same argument, *i.e.*, that "if liability is not found based on individual acts, then none can be found on the acts taken together." *Id.* at 428. In particular, the court explained that "[t]hat argument is contrary to the law," because "[w]hen determining antitrust liability based on a collection of factual allegations, 'the courts must look to the monopolist's conduct taken as a whole rather than considering each aspect in isolation.'" *Id.* (quoting *LePage's Inc. v. 3M,* 324 F.3d 141, 162 (3d Cir. 2003)); *see also Continental Ore v. Union Carbide*, 370 U.S. 690, 699 (1962) ("plaintiffs should be given the full benefit of their proof without tightly compartmentalizing the various factual components and wiping the slate clean after scrutiny of each"), *superseded by statute on other grounds as recognized in In re Intel Corp. Microprocessor Antitrust Litig.*, 452 F. Supp. 2d 555 (D. Del. 2006).

Moreover, Defendants' reliance on *LinkLine* and *Trinko* is misplaced because those cases do not govern exclusionary conduct, but rather cases – unlike this one – that allege a duty to deal with a rival. *Trinko* held that a "firm with no antitrust duty to deal with its rivals at all is under no obligation to provide those rivals with a 'sufficient' level of service." *Pac. Bell Tel. Co. v. LinkLine Communs., Inc.*, 555 U.S. 438, 443 (U.S. 2009) (summarizing holding *Verizon Communs., Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398 (2004)). *LinkLine* extended this principle to alleged "price squeezes."

Id. at 450. The "alchemize" phrase on which Defendants rely so heavily merely stands for the principle that the plaintiff in that case could not salvage an otherwise faltering case by asserting a pricing theory that would not meet the predatory pricing standards of *Brooke Group* or the then-new pleadings standards of *Twombly*. *Id.* at 457.

None of that has any relevance here. This is a classic case about foreclosure and/or exclusionary conduct. Am. Compl. ¶ 96 ("foreclose generic competition"), ¶ 121 ("exclusionary, anticompetitive conduct"); NY PCOL ¶¶ 38-90. New York has described its legal theory, and provided facts in support, that Defendants' conduct harms competition and lacks any legitimate business purpose. Am. Compl. ¶¶ 76-119; NY PFOF ¶¶ 93-168; NY PCOL ¶¶ 38-90. This case is not based on a duty to deal with competitors, let alone a "price squeeze" or predatory pricing. Indeed, the injunction sought by New York would in no way force Defendants to deal in any way with competitors. *See* Am. Compl. at pp. 39-40 (prayer for relief).[2]

C. Withdrawal Of A Product From The Market Is Not Immune From The Antitrust Laws

Defendants appear to suggest that there is special immunity under the antitrust laws for withdrawal of a product form the market. There is no such rule. *See* NY PCOL ¶¶ 38-49. Supreme Court decisions such as *Colgate* and *Trinko* indicate that manufacturers have significant discretion to refuse to sell a product, but that decision is still subject to antitrust oversight. *See United States v. Colgate & Co.*, 250 U.S. 300, 307 (1919) ("*In the absence of any purpose to create or maintain a monopoly*, the [Sherman] act does not restrict the long recognized right of trader or manufacturer engaged in an entirely private business, freely to exercise his own independent discretion as to parties

[2] Moreover, given the detailed factual allegations of the Amended Complaint, and five days of testimony at the preliminary injunction hearing, it cannot reasonably be argued that there is a *Twombly* problem here.

with whom he will deal) (emphasis added); *Verizon Commc'ns Inc. v. Law Offices of Curtis V. Trinko*, LLP, 540 U.S. 398, 408 (2004) ("Under certain circumstances, a refusal to cooperate with rivals can constitute anticompetitive conduct and violate § 2").

In New York's PCOL, New York also discusses numerous cases that considered a product withdrawal to be a valid element of a Section 2 violation. *See* NY PCOL ¶¶ 45-49, 72-73. There is no suggestion in these decisions that a product withdrawal is automatically exempt from antitrust scrutiny.

II. New York Has Pleaded That Forest Monopolized A Relevant Antitrust Market

New York has pleaded facts sufficient to show a relevant market that Forest monopolized (or attempted to monopolize). Am. Compl. ¶¶ 46-51, 98-104; NY PFOF ¶¶ 93-107; NY PCOL ¶¶ 25-37. Defendants even accept the relevant market alleged by New York, at least for purposes of this motion. Defs.' Mem. at 12 n.8.

Nevertheless, under the heading of a supposed failure to allege monopolization of a relevant market, Defendants instead make an ideological argument that – according to them – would excuse their anticompetitive conduct on the basis that it is "innovative." Defs.' Mem. at 11. This argument is flawed because it fails to "distinguish harm that results from anticompetitive conduct from harm that results from innovative competition." *Abbott Labs.*, 432 F. Supp. 2d at 421. New York does not deny that Namenda XR may benefit some Alzheimer's patients. Am. Compl. ¶ 77. However, the *forced switch* is not lawful competition because it involves no "innovative competition" or, more broadly, no "competition on the merits." *Abbott Labs.*, 432 F. Supp. 2d at 421; *Trans Sport*, 964 F.2d at188-89 (distinguishing between "conduct that defeats a competitor because of efficiency and satisfaction" and competition that is not "on the

merits"); *Microsoft*, 253 F.3d at 59, 65 (competition on the merits "involves, for example, greater efficiency or enhanced consumer appeal"). New York challenges the withdrawal of Namenda IR, not the introduction of Namenda XR. Am. Compl. at p. 40 (Prayer for Relief ¶ d). There is nothing about the withdrawal of Namenda IR that benefits consumers or improves the attractiveness of Defendants' products.

Defendants also err in arguing that they cannot be liable for anticompetitive exclusionary conduct or foreclosure unless generic competition is excluded in its entirety. Defs.' Mem. at 11-12 (purporting to refute claims on basis of Forest's projection that, even with the forced switch, generics were nonetheless expected to eventually achieve some diminished portion of sales over an extended period). This is misguided because the test "is not total foreclosure, but whether the challenged practices bar a substantial number of rivals or severely restrict the market's ambit." *United States v. Dentsply Int'l, Inc.*, 399 F.3d 181, 191 (3d Cir. 2005); *Microsoft*, 253 F.3d at 64 (A plaintiff need not show that the Defendants' conduct bars "its rivals from all means of distribution" but rather that it "bar[s] them from the cost-efficient ones."); NY PCOL ¶ 53.

A. The Claim Pursued Here Is A Classic Monopolization Claim

Defendants mischaracterize New York's allegations as if New York were a stand-in for Forest's would-be generic competitors. Defs.' Mem. at 12. This argument has no merit and deserves little attention.[3] Defendants apparently base their accusation on the fact that one of their competitors, [redacted]

[3] New York presented the testimony of Dr. Lah, an Alzheimer's researcher and clinician, who stated that he was concerned about his reduced medical options as a result of Defendants' conduct, and the resulting potential impact on his Alzheimer patients and their caregivers, as well as the testimony David F. Stitt, R. Ph. who testified that health plans would be harmed by the forced switch. NY PFOF ¶¶ 5-12, 14, 18-21, 23, 26-27, 29-30, 41-43, 52, 55-56, 60-61, 69, 81, 84, 87-88, 91-99, 101-102, 105-106, 108, 110, 114, 117, 120, 122-123, 127, 129, 130-131, 136-140, 143-148, 152-153, 157-160, 162-163, 165, 170-178, 184.

[redacted] NY PFOF ¶¶ 12-13, 41-45, 63, 108-112, 130, 134. Am Compl. ¶¶ 2-6, 76-97.

But this action is not and has never been an effort to protect competitors. Rather, it is an effort to protect competition that in turn protects customers – physicians, patients, caregivers, and health plans – from being denied the benefits of competition to which they are entitled under the antitrust laws.[4]

1. New York Does Not Seek To Impose A Duty To Deal With Competitors, And The Relief Sought By New York Is Not Unprecedented

Defendants mischaracterize the relief sought when they argue that, if granted, it would "require courts to assume the day-to-day function of the FDA." Defs.' Mem. at 14. Far from asking the Court to take on the role of a regulatory agency, New York's Prayer For Relief seeks only an order "[e]njoining Defendants preliminarily and permanently from discontinuing Namenda IR until generic memantine is available in the market and for a reasonable time thereafter." Am. Compl. at p. 40. This is not unprecedented, and indeed, it is significantly less onerous than injunctions that have issued in antitrust and other cases. NY PCOL ¶¶ 17-24. If a monopolist runs its business anticompetitively, it will be necessary for a court to order it to behave differently – but that is well within the Court's power and discretion to do. Moreover, issues relating to remedy are best handled at the remedy phase of the case – they are no reason to end a case before it has even started.

[4] Defendants again incorrectly cite *LinkLine* and *Trinko*. Defs.' Mem. at 13 (also citing *Adderall*, 754 F.3d at 135). This is wrong for same reasons stated above, which are incorporated by reference, but not repeated here, to avoid duplication. *See also* NY PCOL ¶¶ 38-39, 82-83, 90.

As noted above, Defendants' reliance on *Berkey Photo* is misplaced, because in that case, the Second Circuit specifically warned of the need to preserve consumer choice. NY PCOL ¶¶ 42-44, 80. Defendants' "3% plan" for distribution through Foundation Care does not preserve consumer choice.

Similarly, *IBM v. Platform Solutions, Inc.*, 658 F. Supp. 2d 603 (S.D.N.Y. 2009), does not support Defendants' motion, because that decision specifically acknowledges that a refusal to deal can constitute an antitrust violation if not based on a legitimate business purpose. To begin with, the court did not dismiss the case on the pleadings, as Defendants seek here – the motion was one for summary judgment. Second, the court stated that the right to refuse to deal "is not unqualified" and explained that a refusal to deal with a competitor can be unlawful where a monopolist "forsake[s] short-term profits to achieve an anticompetitive end." *Id.* at 613. The plaintiff in *Platform Solutions* failed to demonstrate a lack of legitimate business purpose in connection with IBM's actions. But that has no bearing on whether New York will be able to show a lack of business purpose here. The decision in *Platform Solutions* in fact supports New York's view that a refusal-to-deal case should not be dismissed on the pleadings, and requires a careful evaluation of the defendant's actual business purpose (or lack of one) under Section 2 of the Sherman Act.

In addition, as explained in New York's Proposed Conclusions of Law, to the extent that this case *were* treated as a "refusal to deal" case, New York has presented evidence that would in any event satisfy the standards of those cases. *See* NY PCOL ¶ 82-83. In particular, the evidence demonstrates that Defendants, by refusing to sell a drug that physicians and patients want, are sacrificing short term profits in order to

achieve a longer term, anticompetitive objective. *See* Am. Compl. ¶¶ 82, 101-102; NY PFOF ¶¶ 59, 160. New York thus states a claim under the standards of the refusal to deal cases, such as *Trinko*, as well as a standard claim for monopolization based on *Microsoft*.[5]

2 & 3. New York Does Not Seek Subsidies For Anyone And Forest Has No Basis To Question The Policies Set By The Hatch-Waxman Act And State Substitution Laws

Defendants would have the Court believe that generic companies are nothing more than "free riders" that patients would be better off without. Defs.' Mem. at 15. In making this argument, Defendants are doing nothing less than challenging the lawful policies set by the Hatch–Waxman Act and state substitution laws. *See* NY PFOF ¶¶ 5-15. The injunction sought by New York is not a subsidy, but rather seeks to enjoin defendants from interfering with competition as envisioned and carefully laid out by federal and state law. Am. Compl. at p. 40 (Prayer for Relief). In any event, the Hatch–Waxman Act is not on trial here; if Defendants disagree with the law they have means to challenge or seek to change it.[6]

4. The Forced Switch Is Unlawful "Regulatory Gaming"

Defendants miss the point when they ask what law they are breaking if they do not directly break FDA regulations, state substitution laws, or the Hatch–Waxman Act.

[5] New York is not seeking to create a broad, generalized, "duty to deal" with customers. New York notes, however, that the test that the Supreme Court has indicated should govern a determination of whether a refusal to deal with competitors is anticompetitive, would, if applied to the product withdrawal at issue in this case, indicate that Defendants' withdrawal of Namenda IR from the market is anticompetitive.

[6] Defendants' argument concerning the mandatory and permissive state substitution laws is also unpersuasive. To begin, Defendants themselves acknowledge that there is a generic substitution law in all 50 states. Defs.' Mem. at 16 (discussing 11 mandatory substitution and 39 permissive substitution states). Moreover, it is unclear why this matters. Defendants' forced switch scheme will interfere with the operation of both mandatory and permissive substitution laws. None of these facts support Defendants on this motion, and indeed, further support New York's request for a preliminary injunction. In any event, the harm in New York alone would be enough to deny the motion to dismiss and grant the motion for an injunction.

Defs.' Mem. at 17. The answer is that the forced switch violates the Sherman Act, the Donnelly Act, and New York's Executive Law. Am. Compl. ¶¶ 120-32.

B. This Action Seeks To Punish Coercive, Anticompetitive Conduct And Thus Encourage True Innovation.

Defendants make a straw-man argument when they claim that New York seeks to punish innovation. Defs.' Mem. at 17-20. As discussed above, Defendants again fail to "distinguish harm that results from anticompetitive conduct from harm that results from innovative competition." *Abbott Labs.*, 432 F. Supp. 2d at 421. New York concedes that the *introduction* of Namenda XR may provide value to some patients. But New York alleges that the *forced switch by means of the withdrawal of Namenda IR* is not legitimate competition on the merits, but rather, market manipulation. Forest cannot escape this allegation by merely hoisting a banner labeled "Innovation!"

Defendants again err by citing *Berkey Photo*, while failing to acknowledge that in that case, the Second Circuit specifically called out the need to preserve *consumer choice* – exactly the opposite of what Defendants seek to achieve with their forced switch. NY PCOL ¶¶ 42-44, 80. And although Defendants claim that the Foundation Care program allows for consumer choice, that fact is disputed. Offering a choice that Defendants know will work for 3% of patients is not offering a true choice at all. NY PFOF ¶¶ 145-152.

Defendants also misstate the holding of *AstraZeneca AB v. Mylan Labs., Inc. (In re Omeprazole Patent Litig.)*, 2010 U.S. Dist. LEXIS 50049 (S.D.N.Y. May 19, 2010), which did not address a *forced switch*, but rather only an allegation that the introduction of a newer drug *itself* was anticompetitive – i.e., this was a challenge to a "soft switch" not a "hard switch." *Id.* at *22 (the "the alleged conduct" was "introducing new

products," not a forced switch). As repeated above, New York's allegations are not based on the *introduction* of Namenda XR, but rather on the coercive nature of the withdrawal of Namenda IR (i.e., a "hard" or "forced switch,") and its corresponding anticompetitive effects. Am. Compl. ¶¶ 76-119.

New York does not seek to have courts authorize or weigh the sufficiency of innovation. Defs.' Mem. at 21. Indeed, to the contrary: New York seeks to have *the markets* weigh the value of Forest's innovation by leaving both products on the market. New York seeks an injunction against the forced switch scheme because it would interfere with those market forces, for no procompetitive reason. Am. Compl. at pp. 39-40 (Prayer for Relief).

III. New York Alleges Valid Donnelly Act Claims For Unilateral And Multilateral Conduct

Defendants challenge to the Donnelly Act fails for two reasons. (1) the Donnelly Act is not limited to multilateral conduct, and indeed, the word "monopoly" is in the title of the statute itself. *See* NY PCOL ¶¶ 98-100 (citing *inter alia Continental Guest Servs. Corp. v. Int'l Bus Servs., Inc.*, 92 A.D.3d 570, 574 (1st Dep't 2012)); N.Y. Gen. Bus. Law § 340; and (2) the question is in any event moot since the Amended Complaint alleges concerted conduct. Specifically, the Amended Complaint alleges that a key restrictive provision in the agreement between Forest and the mail-order specialty pharmacy in Missouri it chose as its partner for the limited distribution plan constitutes a key part of Defendants' scheme to monopolize, as well as an independently actionable anticompetitive restraint of trade. Am. Compl. ¶¶ 126-28. Even Defendants concede that the Donnelly Act extends to "concerted action by two or more entities and a consequent restraint of trade." Defs.' Mem. at 22 (quoting case). This "concerted action" standard is

a low bar, and even without the undisputed Foundation Care agreement, it would be satisfied by other allegations. *See, e.g.*, N.Y. Am. Compl. ¶¶ 93-97 (concerted action concerning CMS). In any event, since New York makes precisely such an allegation, the claim is validly stated, with or without the allegation of unilateral conduct. Am. Compl. ¶¶ 111, 126-128; NY PCOL ¶¶ 98-104. Therefore, the Court need not address the question of unilateral conduct under the Donnelly Act.

IV. New York Has Stated A Valid Claim Under Executive Law § 63(12)

Defendants misconstrue § 63(12) as applying only to traditional fraud claims as predicates. Defs.' Mem. at 23. This is facially incorrect. To begin, Defendants ignore the "illegal acts" prong of § 63(12). The statute expressly applies to "repeated fraudulent *or illegal acts* or otherwise demonstrate persistent fraud or *illegality* in the carrying on, conducting or transaction of business." N.Y. Gen. Bus. Law § 63(12) (emphasis added). It is well settled that antitrust violations are valid predicates for a § 63(12) claim based on "illegality." NY PCOL ¶¶ 105-11 (citing *State v. Feldman*, 210 F. Supp. 2d 294, 300 (S.D.N.Y. 2002); *State v. Stevens*, 497 N.Y.S.2d 812, 813 (Sup. Ct. Oswego Co. 1985) (violations of federal laws can constitute illegality within meaning of § 63(12)); *In re Dynamic Random Access Memory (Dram) Antitrust Litigation*, 2008 U.S. Dist. LEXIS 86650, at *11-12 (N.D.Ca. 2008)). Here, New York alleges illegality based on violations of the federal Sherman Act. NY PCOL ¶¶ 105-111; Am. Compl. ¶ 130. Defendants' reliance on the elements of a traditional common law fraud claim is therefore misplaced.

Second, New York's § 63(12) claim based on fraudulent conduct is also valid. The term "fraud" has a statutorily defined meaning within the context of Executive Law § 63(12), including "any device, scheme or artifice to defraud and any deception,

misrepresentation, concealment, suppression, false pretense, false promise or unconscionable contractual provisions." N.Y. Exec. Law § 63(12). Consistent with this language and its legislative intent, courts have consistently applied an extremely broad view of what constitutes fraudulent and deceptive conduct in proceedings brought by the Attorney General under Executive Law § 63(12), going well beyond the scope of fraud and deception found at common law. *See, e.g., Lefkowitz v. Bull Inv. Grp., Inc.*, 46 A.D.2d 25, 28 (3d Dep't 1974); *People v. 21st Century Leisure Spa Int'l, Ltd.*, 153 Misc. 2d 938, 943 (Sup. Ct. N.Y. Cnty. 1991). It is thus well-settled that the Attorney General need not make any showing as to the traditional elements of common law fraud, such as reliance or intent to deceive, in order to establish liability for statutory fraud under Executive Law § 63(12). *See People v. Apple Health & Sports Clubs, Ltd.*, 206 A.D.2d 266, 267 (1st Dep't 1994); *21st Century Leisure Spa*, 153 Misc. 2d at 944; *State v. Ford Motor Co.*, 136 A.D.2d 154, 158 (3d Dep't 1988).

The standard for fraudulent conduct under Executive Law § 63(12) is whether the act "has the capacity or tendency to deceive, or creates an atmosphere conducive to fraud." *In re People v. Applied Card Sys., Inc.*, 27 A.D.3d 104, 106 (3d Dep't 2005); *People v. Gen. Elec. Co.*, 302 A.D.2d 314 (1st Dep't 2003). Executive Law § 63(12) thus protects the credulous and the unthinking as well as the cynical and the intelligent, the trusting as well as the suspicious. *See Gen. Elec.*, 302 A.D.2d at 314; *Applied Card*, 27 A.D.3d at 106; *Guggenheimer v. Ginzburg*, 43 N.Y.2d 268, 273 (1977).

New York has met the standard for pleading fraudulent conduct under § 63(12). *See* Am. Compl. ¶ 132 (alleging "repeated fraudulent acts or … persistent fraud by deceptively exaggerating the timing and scope of their plan to discontinue Namenda IR,

as part of an effort to increase the pressure on patients, physicians, and insurers to switch to Namenda XR.")

V. New York Has Properly Alleged An Unlawful Agreement In Restraint Of Trade Under Section 1 And The Donnelly Act

New York has stated a valid Section 1 claim by alleging that a restrictive provision in the contract between Forest and the mail-order specialty pharmacy Foundation Care in Missouri is an unreasonable restraint on trade. *See* Am. Compl. NY PCOL ¶¶ 101-04. The restraint is unreasonable, because it will likely – according to Defendants themselves – prevent Foundation Care from making Namenda IR available to the vast majority (likely all but 3%) of current Namenda IR users. NY FOF ¶¶ 80, 85, 145. Professor Lah testified that some of his patients may not be able to continue getting Namenda IR on the basis of Defendants' "medical necessity" condition of the forced switch. NY PFOF ¶¶ 87-88. *See also* Am. Compl. ¶¶ 111-119, 127-128.

New York alleges that the restrictive provision in the agreement with Foundation Care is intended to further Defendants' efforts to monopolize the market and restrain trade. Absent this restriction, which requires physicians to certify "medical necessity" in order to obtain Namenda IR, many more physicians might be willing to make use of the Foundation Care program to ensure that their patients can stay on Namenda IR. This would potentially provide a more realistic opportunity for physicians and patients to remain on Namenda IR and then switch to the generic version without a disruption in treatment. But the "medical necessity' provision in the Foundation Care contract (as well as that distribution must be by mail and only through *one* distributor in Missouri) prevents this from happening – at least on a broad scale – and that is exactly the purpose of it. Am. Compl. ¶¶ 111, 118; *see generally id.* ¶¶ 105-119.

Defendants have no basis for their half-hearted challenge concerning their conspiracy with Foundation Care under *Bell Atlantic Corp. v. Twombly,* 550 U.S. 544 (2007). Defs. Mem. at 24. *Twombly* requires only that a plaintiff plead "plausible grounds to infer an agreement." *Twombly*, 550 U.S. at 556. Here, there is no dispute that there *is* an agreement. See Defs. Mem. at 7-8 (citing Forest press release stating that it "would continue to make [Namenda IR] tablet[s] available through Foundation Care"); Am. Compl. ¶¶ 111-119 (factual allegations concerning limited distribution, agreement with Foundation Care); PX305 (contract between Forest and Foundation Care).

Defendants' only remaining argument is their assertion that they cannot be liable for their anticompetitive agreement with Foundation Care, under the "intracorporate immunity" doctrine of *Copperweld Corp. v. Independence Tube Corp.*, 467 U.S. 752, 771 (1984). Defs.' Mem. at 25. Specifically, Defendants assert that Foundation Care is Forest's *agent*, and that *Copperweld* does not allows Section 1 claims for agreements between principals and agents. Defendants' argument fails for the simple reason that the contract between Forest and Foundation Care *expressly disclaims a principal-agent relationship*. [redacted]

Because Forest and Foundation Care are *not* in a principal-agent relationship, Defendants' *Copperweld* argument is baseless.

CONCLUSION

For the foregoing reasons, Defendants' Motion to Dismiss should be denied.

Dated: November 21, 2014
New York, New York

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